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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,472	12/29/2000	Dinesh Mody	FMT1P028	7176

28802 7590 02/12/2004

AFX INC.
47929 FREMONT BLVD
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EXAMINER	
SHAY, DAVID M	
ART UNIT	**PAPER NUMBER**
3739	19

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
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☑ This application has been examined ☑ Responsive to communication filed on Jun 24, 1993 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-107, 223-255, 282-300 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 108-224, 256-281 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☑ Claims 1-107, 225-255, 282-300 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-105, 298, and 299 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent regarding the energy delivery portion not being in fluid communication with the tissue region during ablation.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 9, 23, 24, 34-39, 43-47, 55-57, 92-95, and 98 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hussein et al.

Claims 1-4, 9-11, 23, 24, 34-39, 43, 55-57, 80, 82-86, 88-95, 98, 99, 106 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kesten et al in combination with Osypka. Kesten et al teach a device such as claimed except the lack of fluid communication between the tissue and the ablative device. Osypka teaches an ablative device which is fluidicly isolated from the tissue it acts upon. It would have been obvious to the artisan of ordinary skill to employ the ablative device of Kesten et al in the device of Osypka, since Osypka teaches no particular device or, alternatively to employ the fluidic isolation means of Osypka in the device of Kesten et al, since this would shield the distal ends of the conductors from bodily fluids, as taught by Osypka, thus producing a method such as claimed.

Claims 282-297, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al (WO '187) in combination with Kesten et al. The teachings of Kesten et al are essentially those already set forth above. Cox et al (WO '187) teach ablating the pulmonary veins with a variety of energy sources. It would have been obvious to the artisan of ordinary skill to employ the ablation means of Kesten et al in the method of Cox et al (WO '187) since Cox et al (WO '187) provide no particular details of the alternate ablation means; or to provide the probe end configurations of Cox et al (WO '187) in the method of Kesten et al, since these are appropriate for the application of the various energies of Kesten et al, as taught by Cox et al (WO '187) and to apply then to the pulmonary veins, since this provides desirable therapy, as also taught Cox et al (WO '187), thus producing a method such as claimed.

Claims 1-24, 40-48, 65-68, 92-95, 104-107, 298, and 299 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al (WO '187) in combination with Osypka and Kesten et al. The teachings of Osypka and Kesten et al and the motivations for modification and combination thereof are essentially those already set forth above. Cox et al (WO'187) teach ablating the endocardial tissues surrounding the pulmonary veins using a variety of energy sources. It would have been obvious to the artisan of ordinary skill to employ the probes of Kesten et al in the method of Cox et al (WO'187) since Cox et al (WO'187) provide no specifics of the alternative ablation devices or to employ the probe configurations of Cox et al (WO '187) in the method of Kesten et al, since these are suitable for treating the endocardium around the pulmonary veins, and in either case to employ the fluidic isolation means of Osypka, since this would help protect the device from bodily fluids, as taught by Osypka, thus producing method such as claimed.

Claims 225-230, 234, 236, and 240-255 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al in combination with Cox et al (WO'187), and Kesten et al. The teachings of Kesten et al, and Cox et al (WO'187) and the motivations for combination and modification thereof are as already set forth in the rejections above. Swanson et al teach a device for and method of ablating endocardial tissue as well as the equivalence of employing symmetrical shaft configurations to enable rotation and asymmetrical lumen configurations with complimentary shaped inserts to prevent relative rotation thereof. It would have been obvious to the artisan of ordinary skill to employ the alternate energy applicators of Kesten et al in the device of Swanson et al, since these are equivalent as taught by Kesten et al or to employ the asymmetric lumen of Swanson et al in the method of Kesten et al, since these are equivalent in cardiac ablation devices, as taught by Swanson et al and in either case to employ the teachings of Cox (WO '187) for the reasons set forth above; or employ the various energies and energy applicators of Cox et al (WO'187) in the method of Swanson et al, since these are all applicable for creating lesions in the endocardium around the pulmonary veins, as taught by Cox et al (WO '187) or to employ the asymmetric lumen and complementary ablation member of Swanson et al in the method of Cox et al (WO '187) since these are equivalents and prevent undesirable rotation, as taught by Swanson et al; and in either case to employ the teachings of Kesten et al for the reasons set forth above, thus producing a method such as claimed.

Claims 25-33, 49-54, 58-64, 69-79, 81, 86, 87, 92-94, 96, 97, and 100-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein et al or Cox et al (WO '187) in combination with Osypka and Kesten et al. Hussein et al and the combination of Cox et al (WO '187) Osypka and Kesten et al teach methods of ablating cardiac tissue using various forms of

energy, Cox et al (WO'187) particularly teaching treating the heart in the vicinity of pulmonary veins. It would have been obvious to the artisan of ordinary skill to employ ultrasonic, microwave or radio frequency energy, since these are equivalents to the other energies shown by the applied art; to employ a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this is notorious in ablation systems, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective since this is also notorious in the art notice of the notoriousness of all of these having already been taken thus producing a method such as claimed.

Claims 225, 229, 232, 235, 238, and 239 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al in combination with Cox et al (WO '187) and Kesten et al. The combination of Swanson et al, Kesten et al and Cox et al (WO '187) teach methods of ablating cardiac tissue using various forms of energy. Swanson et al and Cox et al (WO '187) particularly teaching treating the heart in the vicinity of pulmonary veins. It would have been obvious to the artisan of ordinary skill to employ ultrasonic, microwave or radio frequency energy, since these are equivalents to the other energies shown by the applied art; to employ a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this is a notorious in ablation systems, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective, since this is also notorious is the art notice of the notoriousness of all of these having been already taken thus producing a method such as claimed.

Applicant argues that the references do not meet the claims due to inter alia a lack of teaching of translumenal positioning in a first and second ablation positions; use of an asymmetric lumen; and preventing fluid communication between the ablated tissue and the ablation device. It is firstly noted, with respect to Hussein et al that the device providing fluidic isolation shown in Figures 1 et seq. thereof can be modified to produce direction of the laser to different area (see e.g. column 5, lines 14-44) which constitutes multiple ablation positions, since multiple positions may be ablated thereby. Similarly the devices of Cox et al (WO '187) and Kesten et al, which teach a device directed through a lumen to ablate various areas constitutes the claimed translumenal first and second positioning.

Regarding the rejection of claims 25-33 at cetera, regarding the dependent claims, applicant merely states "The Examiner should withdraw the rejection" This statement is followed by various arguments drawn only to features of the independent claims, however, since the independent claims are not patentable as set forth above, these rejections have been maintained.

Applicant's arguments filed June 27, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

Applicant's arguments with respect to claims1-107, 225-255, and 282-300 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

Shay/Dl

January 15, 2004